



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7836

July 2, 2002

WARNING LETTER

NWE-22-02W

VIA FEDEX

Jay Mininberg, President
Orange Donuts Inc.
dba Muffin Man Bakery
1408 Whalley Avenue
New Haven, Connecticut 06515

Dear Mr. Mininberg:

On April 3, 4 and 8, 2002, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 1408 Whalley Avenue, New Haven, Connecticut. This inspection was conducted as part of an investigation into a complaint of an allergic reaction by a consumer of "[REDACTED] Chocolate Chip Brownie". During the inspection, our investigator collected labels of brownies that you currently manufacture for [REDACTED].

Our review of these labels revealed that the above product is misbranded pursuant to section 403 of the Federal Food, Drug, and Cosmetic Act (the Act), and Title 21, Code of Federal Regulations (21 CFR), Part 101, Food Labeling. You can find the Act and the Food Labeling regulations through links in FDA's homepage at www.fda.gov.

The label on your Chocolate Chip Brownie label reads in part, "Ingredients: Sugar, enriched flour, partially hydrogenated vegetable oil, whey, dextrose, egg yolks, egg whites, salt, baking soda, corn starch, artificial flavor, margarine."

This product is misbranded in that it fails to list all of the ingredients contained in the brownie by their common or usual names as required by section 403(i)(2) of the Act and 21 CFR 101.4(a)(1). Some of the undeclared ingredients are known food allergens. For example, the label fails to declare soy lecithin and hydrogenated soybean oil. Through interview and observation we know that both of these ingredients are used in the formulation of your brownie.

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Further, enriched flour and margarine (both listed as ingredients in your brownie), contain two or more ingredients. 21 CFR 101.4(b)(2) requires that the flour and margarine be declared in a manner that lists each of their component ingredients. Additionally, under 21 CFR 101.4(b)(14) your product label must declare the common or usual name of each individual fat and/or oil included in the hydrogenated vegetable oil used in your brownie.


The above violations are not meant to be an all-inclusive list of deficiencies in your facility. Other violations can subject the food to legal action. It is your responsibility to ensure that all of your products are in compliance with applicable statutes and regulations. The agency's policy concerning the labeling of allergenic ingredients in food can be found in FDA's Compliance Policy Guide 555.250, "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens" (copy enclosed). Additional information on food allergens may be obtained through FDA's homepage.

You should take prompt action to correct these violations. You should also review the labeling of all your products, take corrective action where appropriate, and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the steps you have taken to correct violations. For corrections that you cannot complete within the 15 working days, state the reason for the delay and your timeframe for completion. Please provide documentation of the corrections as they are made, including copies of any revised labels, and a written plan for preventing these violations in the future.

Please send your reply (and appropriate documentation) to the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, One Montvale Avenue, Fourth Floor, Stoneham, Massachusetts 02180.

Sincerely,



Gary T. Costello
District Director
New England District Office